REMARKS

Reconsideration of this application is respectfully requested.

Claim 1 has been amended to specify that the stabilizer is selected from dimethylhydantoin, derivatives of dimethylhydantoin, urea, and derivatives of urea. Support for this amendment can be found in the specification at, for example, page 9, line 18 to page 10, line 5. Claim 10 has been amended to clarify that the second component is present in the mixture in an amount up to about 30% by weight. Claims 3-6, 15, and 17 have been amended to correct typographical mistakes and errors in chemical nomenclature.

Claims 20-23 have been added. Claims 20-22 recite an antimicrobial composition comprising a mixture of dimethyloldimethylhydantoin and monomethyloldimethylhydantoin, dimethylhydantoin, and dehydroacetic acid or a salt thereof. Support for these claims can be found in the specification at, for example, page 9, lines 10-13, page 10, lines 16-17, page 11, lines 6-9, and page 17, lines 1-3 (Table 4). Claim 23 recites an antimicrobial composition free of isothiazolones. Support for this claim can be found in the specification at, for example, page 2, line 22 to page 3, line 12 and page 11, lines 3-5 (Table 1). No new matter has been added.

Claims 1-23 are pending. Because claims 5 and 12-19 have been withdrawn from consideration, only claims 1-4, 6-11, and 20-23 are at issue.

I. Restriction and Election of Species Requirement

In the April 27, 2007 Office Action, the Examiner states that claim 5 has been withdrawn from consideration since it is directed to a non-elected species. Applicants respectfully disagree. In a prior response filed December 13, 2006, applicants elected claims 1-11 (Group I) for examination. Applicants also were required to elect a particular aldehyde donor or mixture of aldehyde donors, and elected a mixture of dimethyloldimethylhydantoin and monomethyloldimethylhydantoin.

Claim 5 recites that the aldehyde donor is selected from a group that includes the genus "methylolhydantoins [and mixtures thereof]." The elected species falls within this genus as it is a mixture of two methylolhydantoins. Accordingly, applicants submit that claim 5 is readable on the elected species and respectfully request that it be rejoined with the claims under consideration.

II. Indefiniteness Rejection

Claim 10 has been rejected under 35 U.S.C. §112, second paragraph, as indefinite. According to the Examiner, the limitation that the second component is present in the mixture in an amount of between about 0% and 30% by weight is vague and indefinite because claim 1, the antecedent of claim 10, requires that the second component is present—i.e., that it cannot have a weight percent of 0.

Claim 10 has been amended to specify that the second component is present in the mixture in an amount "up to about 30% by weight." As amended, claim 10 includes each limitation of claim 1 and does not specify a lower limit for the amount of the second component. Accordingly, applicants submit that Claim 10 is definite and request that the rejection be withdrawn.

III. Anticipation Rejection

Claims 1, 2, 7, and 10 have been rejected under 35 U.S.C. §102(b) as anticipated by Hahn et al. (U.S. Patent No. 5,804,203) as evidenced by Rosenthal et al. (U.S. Patent No. 4,585,656) and Patel et al. (U.S. Patent Pub. No. US 2003/0207908). According to the Examiner, Hahn discloses a topical composition comprising an aldehdyde donor (imidazolidinyl urea), stabilizers (disodium EDTA and methylparaben), and a salt of dehydroacetic acid (sodium dehydroacetate). The background references are relied upon as evidence that disodium EDTA and methylparaben are stabilizers.

Claim 1 has been amended to specify that the stabilizer is selected from dimethylhydantoin, derivatives of dimethylhydantoin, urea, and derivatives of urea. Disodium EDTA and methylparaben are not members of the specified classes of stabilizers. Hahn fails to teach or suggest an antimicrobial composition comprising, *inter alia*, one or more aldehyde donors and a second component including one of the specified stabilizers. Accordingly, Hahn does not anticipate claim 1 as amended, and applicants respectfully request that the rejection be withdrawn.

IV. Obviousness Rejections

Claim 3 has been rejected under 35 U.S.C. §103(a) as obvious over Hahn in view of Dodd et al. (U.S. Patent Pub. No. US 2002/0176879). The Examiner contends that although Hahn does not specifically disclose dimethyloldimethylhydantoin ("DMDMH"), Dodd teaches that they are interchangeable with imidazolidinyl urea, the aldehyde donor disclosed by Hahn.

Hahn fails to teach or suggest an antimicrobial composition comprising a combination of an alkanol-substituted dimethylhydantoin aldehyde donor and a stabilizer selected from dimethylhydantoin, urea, and derivatives thereof as presently claimed. Dodd fails to cure this deficiency because it also does not teach such a composition. Accordingly, the combination of Hahn and Dodd fails to teach the present invention. Furthermore, as discussed below, the presently claimed compositions have unexpectedly superior antimicrobial activity. This activity is neither disclosed nor suggested in Hahn or Dodd. Accordingly, Hahn alone or in combination with Dodd fails to render obvious claim 3, and Applicants respectfully request that this rejection be withdrawn.

Claims 1-4 and 6-11 have been rejected under 35 U.S.C. §103 as obvious over Rothenburger (U.S. Patent No. 6,121,302) in view of Willingham (U.S. Patent No. 5,424,324). According to the Examiner, Rothenberger teaches a stabilized preservative formulation comprising (a) an isothiazolone compound, (b) a formaldehyde donor, such as hydantoins (e.g., alkanol-substituted dimethylhydantoins), (c) a stabilizer, such as hydantoins, urea, or their derivatives, and

(d) a solvent, such as water or a hydroxyl solvent. *See* col. 2, line 65 to col. 4, line 54 of Rothenberger. According to the Examiner, Willingham teaches the use of carbonyl compounds, such as dehydroacetic acid, as stabilizers of isothiazolones with the added benefit of antimicrobial activity. *See* col. 4, lines 37-42 of Willingham. The Examiner contends that it would have been obvious to add dehydroacetic acid to the composition of Rothenburger for its stabilizing effect and antimicrobial activity.

Both Rothenburger and Willingham relate to preservative formulations containing isothiazolones. Isothiazolone is highly toxic and unstable under most circumstances, including in the presence of water. Its stability is also a function of temperature of pH, which may rise during storage. The instability of isothiazolone results in a loss of preservative activity. Col. 1, lines 52-65 of Rothenburger. The present invention does not relate to isothiazolones and does not require an isothiazolone stabilizer. One of ordinary skill in the art would not have been motivated to produce a combination of the antimicrobial composition as presently claimed (a combination of an aldehyde donor, a stabilizer selected from dimethylhydantoin, urea, and derivatives thereof, a dehydroacetic acid or salt thereof) and an isothiazolone because of the above shortcomings known in the art.

Nevertheless, although Willingham mentions dehydroacetic acid as a potential stabilizer for isothiazolones, Willingham also teaches away from using organic stabilizers due to their volatility, cost, potential toxicity, handling difficulties, and tendency to decompose under high heat. Col. 1, lines 60-63. Also, Willingham teaches that formaldehyde-releasing chemicals should be avoided in applications where skin contact is possible. Col. 1, lines 50-51 and 64-66. It would not have been obvious to one of ordinary skill in the art to add dehydroacetic acid to the composition of Rothenburger because Willingham teaches away from such a composition by discouraging use of organic stabilizers and formaldehyde-releasing chemicals.

Furthermore, the synergistic antimicrobial activity of the presently claimed composition was unexpected and would not have been obvious to the skilled artisan. The principle of synergism is described in the specification as follows:

A synergistic effect is a response to a combination of two or more components that produce an effect greater than the sum of their individual effects. One method for determining whether a composition exhibits a synergistic effect is the method described in C.E. Kull *et al.*, "Mixtures of Quaternary Ammonium Compounds and Long-chain Fatty Acids as Antifungal Agents", *Applied Microbiology*, 9:538-541 (1961). The synergism value is determined by the formula:

$$Q_A/Q_a + Q_B/Q_b$$

where Q_A is the quantity of Compound A in mixture, producing an endpoint; Q_a is the quantity of Compound a acting alone, producing an endpoint; Q_B is the concentration of Compound B in the mixture, producing an endpoint. Q_b is the concentration of Compound b acting alone, producing an endpoint.

When the value of $(Q_A/Q_a + Q_B/Q_b)$ is less than one, the mixture is synergistic.

(Specification at page 14, lines 5-16.)

A preservative challenge test was performed against mixed bacteria by measuring the levels of Glydant® 2000 (a 70% solution of hydantoin species including about 36% dimethyloldimethylhydantoin, about 29% monomethyloldimethylhydantoin, and about 5% dimethylhydantoin) and dehydroacetic acid (DHA) that were effective against the bacteria. A mixed bacteria was added to test samples of formulations having varying levels of the individual components, and the test samples were incubated. At 0, 7, and 14 days, diluted aliquots of the test samples were incubated on tryptic soy agar plates. Readings of the total number of colony forming units per gram (cfu/g) were made on each sample. *See* specification at page 15, line 13 to page 16, line 6.

The results, illustrated in Table 3 in the specification, show that, individually, 0.05% of Glydant® 2000 and 0.20% of DHA, and a mixture of 0.025% Glydant® 2000 and 0.075% DHA,

each achieved less than 10 cfu/g after 14 days. The calculated value of $(Q_A/Q_a + Q_B/Q_b)$ was 0.87. *See* Table 4 of the specification. Accordingly, the combination of the components demonstrated a synergistic effect.

Evidence of greater than additive (i.e., synergistic) effect is persuasive of nonobviousness where the synergy was not expected. *See Ex parte The NutraSweet Co.*, 19 USPQ2d 1586, 1589 (Bd. Pat. App. & Inter. 1991); *see also* MPEP § 716.02(a) I. None of the cited references disclose or suggest that a synergistic effect would be achieved by combining the components as presently claimed. Accordingly, Applicants submit that the claims are not obvious and respectfully request that the rejection be withdrawn.

V. New Claims 20-23

New claims 20-22 are directed to an antimicrobial mixture comprising a mixture of dimethyloldimethylhydantoin and monomethyloldimethylhydantoin, dimethylhydantoin, and dehydroacetic acid or a salt thereof. An embodiment of this mixture is described in the specification in connection with the preservative challenge test described above and the synergistic results illustrated in Tables 3 and 4.

None of the cited references disclose or suggest such a mixture or its synergistic antimicrobial activity. Accordingly, for at least these reasons claims 20-22 are also allowable over the prior art of record.

New claim 23 recites the antimicrobial composition of claim 1 wherein the composition is free of isothiazolones. The references cited by the Examiner (Rothenburger and Willingham) are directed to preservative formulations containing isothiazolones. Therefore, in addition to the reasons set forth above with respect to claim 1, Applicants submit that claim 23 is also allowable because the prior art does not teach the presently claimed composition free of isothiazolones.

CONCLUSION

In view of the above amendments and remarks, Applicants believe the pending application is in condition for allowance. If there are any remaining issues that the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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